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Select Agent Program
Centers for Disease Control and Prevention
1600 Clifton Road, N.E.
Mail Stop E-79
Atlanta, GA 30333

I am writing in response to the Centers for Disease Control and Prevention's solicitation for comments on 42 CFR Part 73, Interim Final Rule, Possession, Use, and Transfer of Select Agents and Toxins published in the Federal Register, Vol. 240, No. 67 on Friday, December 13, 2002.

Over the past several months I have been working closely with the University's Chief of Police as well as researchers, our biosafety program manager and a Bioterrorism Task Force to find appropriate, meaningful and responsive ways and tools to comply with the fast emerging new requirements. It is a complex task in a higher education research institution. It will be excellent to now have clear and final requirements in place. However it will be much better if the draft requirements of 42 CFR Part 73 contain the modifications carefully developed by my respected colleagues and reported to you by W. Emmett Barkley of Howard Hughes Medical Institute (HHMI).

On behalf of the University of Washington and as the designated "Responsible Official", I support the comments and recommendations for 42 CFR Part 73 submitted by the HHMI on January 21, 2003. I have attached a copy of the HHMI "Comments on 42 CFR Part 73" for your reference. Specifically, the basis for my support and endorsement is that the recommendations will ensure the appropriate availability of biological agents and toxins for research, education, and other legitimate purposes and will make the safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin risk-based. These provisions are requirements of the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002." I particularly support the comments on subsection 73.4 regarding the recommended deletion of Cercopithecine herpesvirus 1 (CHV-1) and also those comments regarding the option for a single certificate of registration under subsection 73.7 (f). Generally, the adoption of the recommendations of the HHMI will lessen the administrative burden of the Final Rule, allow for an effective performance-based security plan, and ensure the relevance of the Final Rule to the biomedical research environment. They address the key issues around which we at the University of Washington have had concerns.

I appreciate the opportunity to comment on the Interim Final Rule.

Sincerely,

Karen A. VanDusen
Director

Enclosure: Comments on 42 CFR Part 73, Interim Final Rule
Possession, Use and Transfer of Select Agents and Toxins

cc: Albert Berger, John Coulter, Vicky Peltzer, Barbara Perry

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